

ACCOMPANYING LABELING: Promotional form letter entitled "Dear Doctor" and leaflet entitled "Are opiates now outmoded in pediatric diarrhea?"

LIBELED: 8-1-61, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article "acts almost exclusively to inhibit gastrointestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine like effects when given in the recommended dosage" and that the "only side effect noted was a mild, more or less transient flushing of the skin"; will successfully treat diarrhea, which threatens pediatric patients, without side effects; and stop diarrhea rapidly, without side effects; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and it was not exempt from the requirement since the promotional material for the new drugs was not the same as, or substantially the same as, the labeling authorized by the effective new drug applications; and 505(a)—the effective new drug application did not apply to the conditions for which the articles were promoted to the medical profession, namely, for the treatment of complications of severe pediatric diarrhea-dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen, and constant crying; nonspecific digestive upsets and for nausea and vomiting.

DISPOSITION: 10-18-61. Default—destruction.

#### DRUG FOR VETERINARY USE

6862. Zoamix medicated feed premix. (F.D.C. No. 46851. S. Nos. 6-468 T, 7-342 T.)

QUANTITY: 63 50-lb. bags at Augusta, Maine.

SHIPPED: 10-25-61 and 11-28-61, from Newark, N.J.

LABEL IN PART: "ZOAMIX A Premix Medicated \* \* \* For Chickens Only. Active Ingredients: Zoalene (3.5-Dinitro-O-Toluidamide) 25%."

RESULTS OF INVESTIGATION: The manufacturer of the article had filed a new drug application which was effective with respect to shipments of the article made to feed manufacturers who had filed effective supplemental new drug applications covering the use of the article in finished feeds. Investigation revealed that the article had been purchased by a dealer at Augusta, Maine for use in the feeds which he manufactured but that such dealer had not filed a supplemental new drug application which was effective for such use.

LIBELED: 12-13-61, Dist. Maine.

CHARGE: 505(a)—the article was a new drug, and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: 1-3-62. Default—destruction.

#### DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6863. Various prescription drugs. (F.D.C. No. 46109. S. Nos. 50-529/33 R, 50-535/8 R.)

QUANTITY: 6,431 tablets and capsules and 70 clips of vials, btl., and packs, at Denver, Colo., in possession of Earl Meyer Drug Co.

SHIPPED: On unknown dates, by various drug handlers.